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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,954	01/30/2001	Yang Wang	P1041PICI	5556
9157	7590	11/22/2005	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/774,954

Applicant(s)

WANG ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-41 is/are rejected.
- 7) ☒ Claim(s) 33 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/30/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence alignment.

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Preliminary Amendment filed January 30, 2001 is acknowledged. Claims 1-30 have been cancelled; new claims 31-41 have been entered. Claims 31-41 are under examination.

### **Detailed Office Action**

#### **1. Election/restriction**

On September 21, 2005, the examiner issued, inadvertently, the Restriction Requirement on claims as originally filed. The Applicant filed Response to Restriction and Election Requirement on Oct. 6, 2005 to meet requirements 37 CFR 1.143. On October 4, 2005, the Applicant's representative Bonny G. Yeung called the examiner, indicating that the restriction requirement was issued in error, and asked to act on the claims of the preliminary amendment. Since the restriction requirement of September 21, 2005 was improper, it is withdrawn by the examiner. Claims 31-41 of the preliminary amendment, directed to one invention, which is a nucleic acid molecule encoding O-fucosyltransferase and related subjects, are under examination.

#### **2. Objections**

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

#### **3. Rejections**

### **3. 1. 35 USC section 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **3.1.1. Lack of written description**

Claim 31-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a DNA molecule encoding O-fucosyltransferase enzyme which is capable of glycosylating an epidermal growth factor, wherein said enzyme is selected from the group consisting of:

- 1) a polypeptide comprising SEQ ID NO: 9
- 2) a polypeptide comprising SEQ ID NO: 2, and
- 3) a polypeptide comprising SEQ ID NO: 3.

The claims are directed to large genera of DNA molecules missing written description of structure. The specification provides sufficient description for genus 2) because it teaches SEQ ID NO: 1 and 16 which are cDNA and OFR of the full length human O-fucosyltransferase set forth by SEQ ID NO: 2. The genus listed under 1) is lacking sufficient written description, because, although the function is stated, the

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structure is only partially described. SEQ ID NO: 9 consists of the first 61 amino acid residues of the N-terminal of SEQ ID NO: 2. Although the full SEQ ID NO: 2 has enzymatic activity, Applicants do not teach the function-structure relationship for SEQ ID NO: 2. Particularly, the specification is silent as to whether SEQ ID NO: 9 comprises catalytic center, so that SEQ ID NO: 9 could transfer the O-fucosyl transferase activity to a polypeptide within which it is comprised. SEQ ID NO: 2 consist of 365 amino acids, and one skilled in the art doubts that replacing amino acids 62-365 with any amino acid sequence will result in an active enzyme. It is frequent in the art that changing even one amino acid residue in a sequence inactivates an enzyme or changes its activity. In conclusion, providing the first 61 amino acids of the N-terminal of SEQ ID NO: 2 and the requirement of function is not sufficient as identifying characteristics of the claimed polypeptide.

Regarding genus 3) the disclosure teaches only 61 amino acid residues of the N-terminus of the O-fucosyltransferase isolated from Chinese hamster cells. The specification does not teach whether amino acid sequence set forth as SEQ ID NO: 3 possesses the enzymatic activity. For that reason the enzymatic activity of any polypeptide comprising SEQ ID NO: 3 is doubtful. Stating the enzymatic function and N-terminal amino acid sequence is not an identifying characteristic of the broadly claimed genus of polypeptides.

For the presented reasons, one skilled in the art is not convinced that applicants were in possession of the claimed invention when the application was filled.

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### 3.1.2. Scope of enablement

Claim 31-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for human O-fucosyltransferase set forth by SEQ ID NO: 2 and its encoding DNA of SEQ ID NO: 1 and 16, does not reasonably provide enablement for a DNA molecule encoding O-fucosyltransferase enzyme which is capable of glycosylating an epidermal growth factor, wherein said enzyme is consisting of:

- 1) a polypeptide comprising SEQ ID NO: 9
- 2) a polypeptide comprising SEQ ID NO: 3.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required to make the invention are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The Wands factors are (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and the breadth of the claim.

The nature of the invention is the DNA molecule encoding a polypeptides comprising SEQ ID NO: 9 or SEQ ID NO: 3 and having O-fucosyltransferase activity. The claims are directed to extremely large genera of DNA molecules for which the

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structure the specification does not provide enabling description of structure. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality intended by Applicants. The provision of SEQ ID NO: 3 or SEQ ID NO: 9 fails to provide a guidance of polynucleotides which encode the enzyme of the required activity, because neither SEQ ID NO: 3 nor SEQ ID NO: 9 are disclosed as possessing the enzymatic activity. Applicants did not provide any example or guidance how to construct the claimed DNA molecules. Therefore, to make the invention one skill in the art had to determine the region of SEQ ID NO: 1 or 16 that encodes the desired activity. In addition one skilled in the art has to sequence the Chinese hamster protein and to find the region of the sequence responsible for the required activity. Alternatively, to make the claimed invention the skilled artisan has to design the full-length enzyme him/herself. Even if one skilled in the art succeeds in the task, his/her enzyme will not be the enzyme disclosed in by Applicant. Applicant disclosed the human enzyme of SEQ ID NO: 2, and Applicant isolated the Chinese hamster protein having the O-fucosyltransferase activity and SEQ ID NO: 3 at its N-terminus. Without a further guidance on the part of Applicants with regards to the structure the claimed invention experimentation left to those in the art is improperly extensive and undue.

### **3. 2. 35 USC section 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 31, 32, 34-35, 37-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Nagase T. et al. (Prediction of the coding sequences of unidentified human genes. V. The coding sequences of 40 new genes (KIAA0161-KIAA0200) deduced by analysis of cDNA clones from human cell line KG-1, DNA Res., 3(1), 17-24 Feb. 29, 1996), included in the Information Disclosure Statement.

The claims are directed to a nucleic acid molecule that encodes a human O-fucosyl transferase enzyme wherein the enzyme comprises SEQ ID NO: 2 or SEQ ID NO: 9, or the nucleic acid sequence comprising SEQ ID NO: 16. Furthermore, the claims are directed to a vector comprising said nucleic acid molecule and a host cell comprising said vector.

Nagase et al. disclose cDNA encoding the enzyme having in positions 24-388 the amino acid sequence identical to SEQ ID NO: 2 of the instant application. The protein disclosed by Nagase et al. comprises SEQ ID NO: 9 which consists of the first 61 N-terminal amino acid residues of SEQ ID NO: 2. Nagase et al. disclose also a vector for expression the DNA encoding the protein comprising SEQ ID NO: 2 or SEQ ID NO: 9 of the instant invention; see the enclosed sequence alignment.



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#### 4. Conclusion

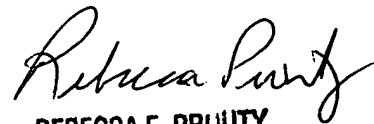
Claims 31-41 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
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Patent Examiner

  
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